GUARDIAN

Focused on Safety

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Kickoff Meeting

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Uwe Trinks, CIO

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Source: https://www.industrydocuments.ucsf.edu/docs/lxpj0001

Agenda

- Introductions
- Guardiant Risk Management Concept
- Overview of Guardiant SafetyTrak® Toolkit
- Guardiant OnTrak™, Registration and Scheduling
- Guardiant SurveyTrak™, Medical Survey and Evaluation
- Guardiant EventTrak™, Adverse Event Intake & Investigation

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Centralized Reporting Concept

Consumer
Reporter
Physician

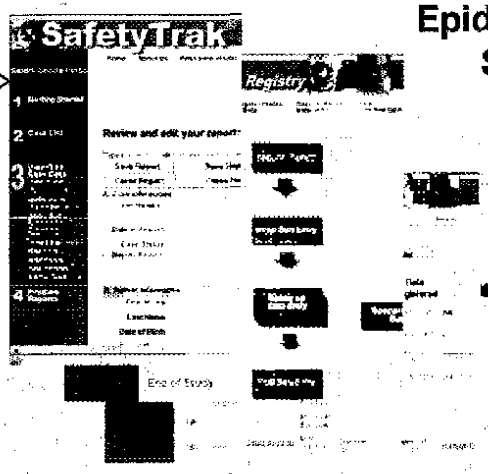
Web Access

E-mail Request

Inbound
Call/Fax

Outbound
Call/Fax

Guardiant Safety
Response Center



Register Physicians/Patients
Schedule Medical Interview
Collect Information
Investigate Cases of Interest
Manage AE Cases

Physicians
Safety
Specialists
Epidemiologists
Statisticians

Real
time
access

SafetyTrak®
Database

XML-, CSV or
SAS Export

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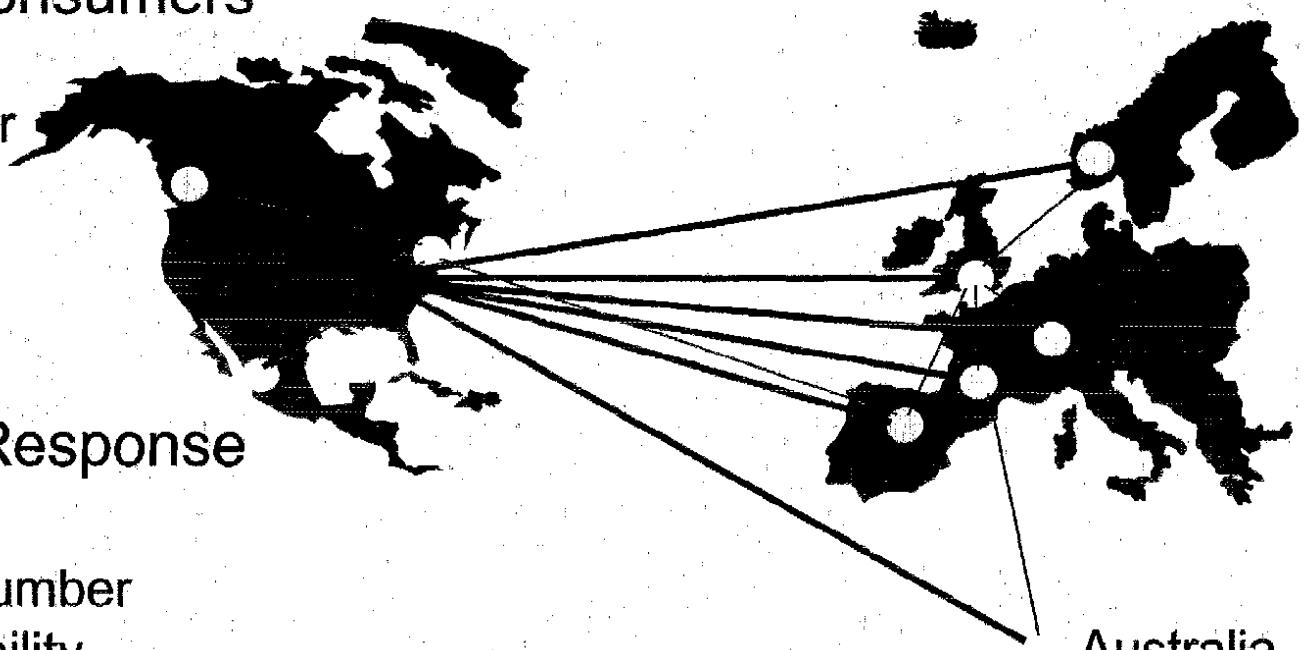
Standardized Process Worldwide for Reporting

- Direct Entry by Consumers
  - 24x7x365
  - Any Web browser
  - Highly structured
  - Auto-QC
  - Ultra-secure



- Regional Safety Response Centers
  - Global toll-free number
  - 24x7x365 availability
  - Follow-the-sun
  - Data entered into same database
  - Study details immediately available

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SafetyTrak® Tools

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Sentrx SafetyTrak® Toolkit

Solution / Module	Clinical Trial Safety	Post-Marketing Safety	Risk Management
OnTrak™ Manages the registration and interview schedule of program participants			✓
EventTrak™ Provides browser-based intake and management of adverse event cases		✓	✓
SurveyTrak™ Directs interactive medical interviews, self-administered on the Web or via phone to the Safety Response Center			✓
StudyTrak™ Enables intelligent intake and management of SAE information across multiple trials, investigators and CROs	✓		
CaseTrak™ Provides workflow and tracking of paper-based AE cases with bar-code technology	✓	✓	

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Sentrx SafetyTrak® Toolkit

Reporting

OnTrak

Registration
Consent
Scheduling
Progress Report
"Follow me"

SurveyTrak

Masking Questions
Trigger Question
Logic Layer
Drill down
Follow up

EventTrak

Adverse Events
Events of Interest
Intake
Investigation

Special Cases

Investigation
Labs etc.
Drop outs
Pregnancy, Cancer

Common Database Layer (E2BM, CDISC)

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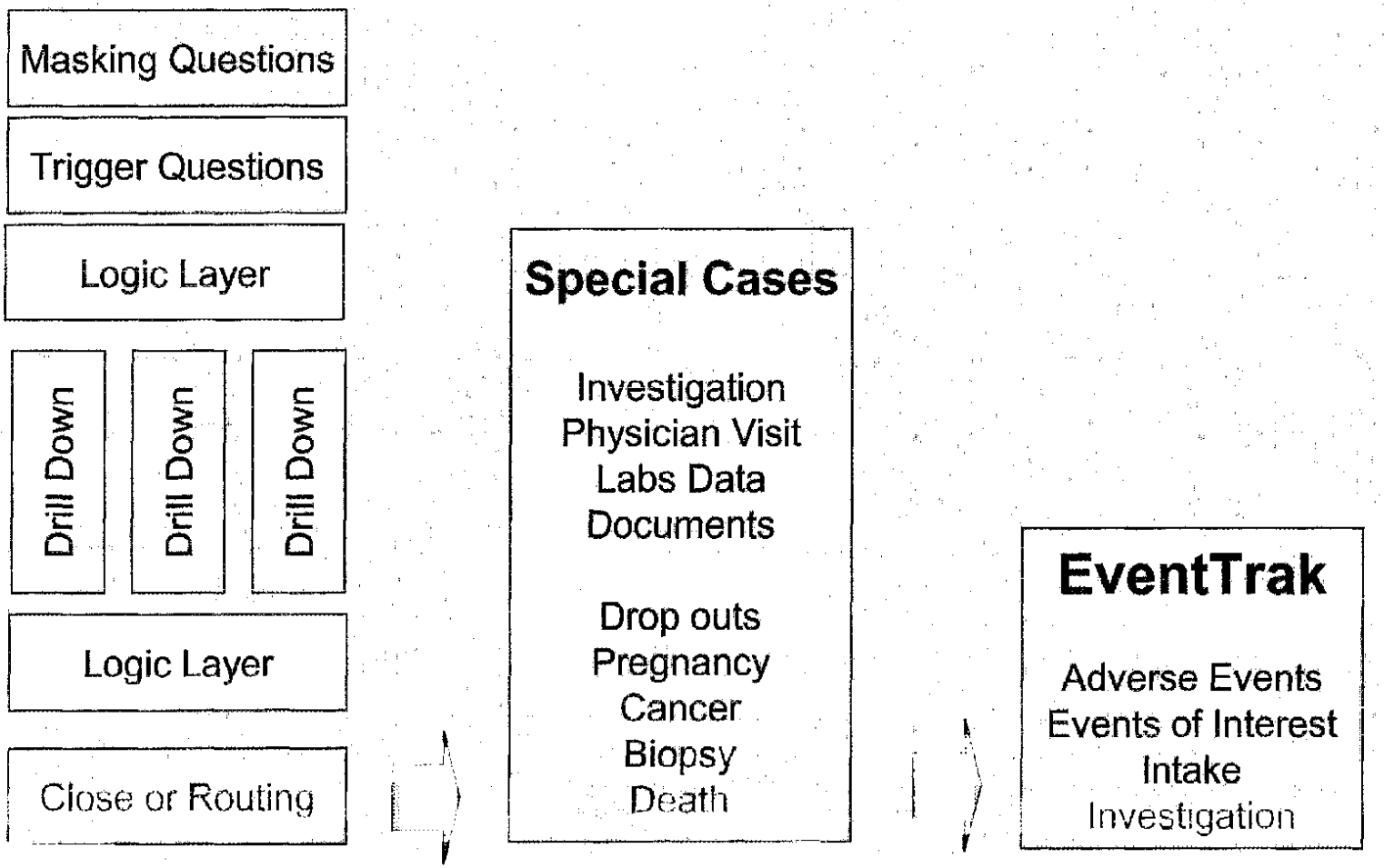
Sentrx SurveyTrak™



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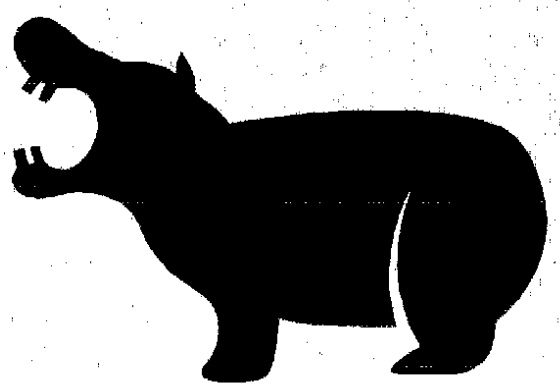
Protected Health Information (PHI)

- PHI is individually identifiable health information
  - Patient Charts
  - Medical Billing Records
  - Insurance Records
  - Clinical Research Records
  - Safety Records
- In any shape or form
- In connection with healthcare treatment, payment or operations in connection with a prescription
  - Independent if it is processed or received by a covered entity or if it is received from a covered entity by a non-covered entity
- As long as it contains any one of the 18 individual identifiers



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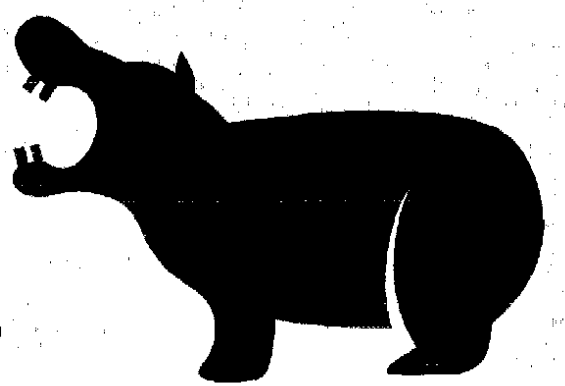
PHI Identifiers

- Names
- Geographic subdivisions smaller than State
- All elements of dates (except year) directly related to an individual (birthday, date of death, date of hospitalization)
- Telephone numbers, Fax numbers, Electronic mail addresses
- Social security number, Medical record numbers
- Health plan beneficiary numbers, Account numbers
- Certificate/license numbers (e.g license plates)
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, like finger or voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic, or code, except as permitted for re-identification.



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Reporting Tools

Instructions

Enrolled Patients

Adverse Events

	Month to Date	Quarter	Year to Date
Serious, Unlabeled		5	15
		13	
		23	78

SAE Alerts

Event Summary

- Angina
- Myocardial Infarction
- Hypertension
- Injection Site Rash

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